DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date APR 17 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Biocompatibles, Inc.'s Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by Eleanor M. Felton, CDRH, HFZ-460, November 27, 1996, 594-1744

1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. _____]

Biocompatibles, Inc.; PREMARKET APPROVAL Of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses For Extended Wear

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Biocompatibles, Inc., Norfolk, VA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. The device is to be manufactured under an agreement with Ciba Vision Corp., Duluth, GA, which has authorized Biocompatibles, Inc. to incorporate information contained in its approved premarket approval applications for the Softcon® E.W. (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 17, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

B

FOR FURTHER INFORMATION CONTACT:

James F. Saviola,
Center for Devices and Radiological Health (HFZ-460),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-1744.

SUPPLEMENTARY INFORMATION: On November 12, 1996, Biocompatibles, Inc., Norfolk, VA 23507, submitted to CDRH an application for premarket approval of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. The device is a soft (hydrophilic) contact lens and is indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in aphakic persons (after cataract surgery) that are myopic or hyperopic. Soft-55 EW Aphakic Lenses may be worn by persons who may exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The application includes authorization from Ciba Vision Corp., Duluth, GA 30136-1518, to incorporate information contained in its approved premarket approval applications for Softcon® E.W. (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory

4

Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On April 17, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

The labeling of the Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear states that the lens is to be used with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory

committee of experts. A petition is to be in the form of a petition for reconsideration 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Hahn
Director of Regulatory Affairs
Biocompatibles, Inc.
1215 Boissevain Avenue
Norfolk, VA 23507

APR 17 1997

Re: P960039
Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear
Filed: November 12, 1996
Amended: November 26, 1996

Dear Ms. Hahn:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. This device is indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in aphakic persons (after cataract surgery) that are myopic or hyperopic. Soft-55 EW Aphakic lenses may be worn by persons who may exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

Expiration dating for this device has been established and approved at 6 years and 4 months. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

9

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Eleanor M. Felton or James F. Saviola, O.D. at (301) 594-1744.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10

Enclosure

Issued: 5-2-95

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

11

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant**(s)** involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

12

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

13

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

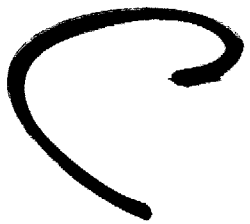
Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

14



Summary of Safety and Effectiveness Data

I. General Information

A. Device Generic Name: vifilcon A soft (hydrophilic) contact lens

B. Device Trade Name: Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear

C. Applicant's Name and Address: Biocompatibles, Inc.
1215 Boissevain Avenue
Norfolk, VA 23507

D. Premarket Approval Application (PMA) Number: P960039

E. Date of Notice of Approval to Applicant: April 17, 1997

II. Indications

The Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. This device is indicated for extended wear from 1 to 7 days as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in aphakic persons (after cataract surgery) that are myopic or hyperopic. Soft-55 EW Aphakic lenses may be worn by persons who may exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

III. Center for Devices and Radiological Health (CDRH) Decision

The application includes by reference the data in PMAs N17-554 and P820021 and related supplements for the Softcon® E.W. (vilficon A) Contact Lenses for Extended Wear submitted by Ciba Vision Corporation and approved by FDA on June 30, 1978 and March 31, 1983, respectively. Ciba Vision Corporation has authorized Biocompatibles, Inc. to incorporate by reference the information contained in its approved PMAs to manufacture the lens by the lathing technique.

CDRH approval of the Biocompatibles, Inc. PMA is based on (1) the safety and effectiveness data contained in PMA N17-554 and P820021 and related supplements and (2) the results of the FDA inspection of the manufacturing facility. A summary of safety and effectiveness data for the Softcon® E.W. (vilficon A) Soft (Hydrophilic) Contact Lenses for Extended Wear appears in Attachment A.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. CDRH issued an approval order on April 17, 1997. The sponsor's manufacturing facility was inspected on November 5, 1996 and was found to be in compliance with the device Good Manufacturing Practice regulations.

The device shelf-life has been established and approved at 6 years and 4 months.

IV. Approval Specifications

Directions for use: See the labeling (Attachment B)

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events sections in the Labeling (Attachment B)

Postapproval Requirements and Restrictions: See approval order

Attachments A and B

Attachment A.

Summary of Safety and Effectiveness Data

I. General Information

A. Device Generic Name: vifilcon A soft (hydrophilic) contact lens

B. Device Trade Name: SOFTCON® (vifilcon A) Contact Lens

C. Applicant's Name and Address: American Optical Corporation
55 New York Avenue
Framingham, Massachusetts 01701

D. Premarket Approval Application (PMA) Number: P820021

E. Date of Panel Recommendation: May 25, 1982

F. Date of Notice to Applicant: Mar. 31, 1983

II. Indications

The SOFTCON® (vifilcon A) Contact Lens is indicated for extended wear for the correction of visual acuity in aphakic persons with non-diseased eyes who have no more than 2.00 diopters of astigmatism.

III. Device Description

The SOFTCON® (vifilcon A) Contact Lens is a hemispherical shell with the following dimensions:

Diameter: 14.0 mm and 14.5 mm
Center thickness: 0.27 mm to 0.44 mm, according to power
Base curve: 8.1 mm, 8.4 mm, 8.7 mm
Powers: +8.00 to +18.00 diopters in 0.50 diopter increments

The lens material, vifilcon A, is a hydrophilic copolymer of 2-hydroxyethylmethacrylate and povidone USP. The physical properties of the lens are:

Refractive index: 1.415
Light transmittance: 96.9%
Water content: 55% by weight in normal saline
Posterior surface: lenticulated, spherical base curve

IV. Alternative Practices or Procedures

Alternative vision correcting practices and procedures available to the patient are another type of contact lens, spectacles or intraocular lenses for the same indications.

V. Summary of Studies

The SOFTCON® (vifilcon A) Contact Lens is the subject of two previous premarket approval applications (PMAs) submitted by American Optical and approved by FDA for therapeutic wear (N17-375) and for vision correction in aphakic persons on a daily wear basis (N17-554).

A. Preclinical:

1. Toxicology: The present PMA includes, by reference to PMAs N17-375 and N17-554, the results of tests outlined in "Toxicological Testing of New Contact Lenses and Soaking/Wetting Solutions Used with New Contact Lenses," a Food and Drug Administration (FDA) Guideline. The tests included, where applicable, in vitro determination of the lens material's toxicity potential; in vitro testing of the toxicity potential of the lens material in combination with recommended soaking/wetting solutions; acute irritation and toxicity tests in laboratory animals; and use tests in laboratory animals with ophthalmoscopic observation and evaluation of gross pathology, histopathology, and corneal metabolism. Similar tests were conducted on the lens packaging, carrying case, and disinfection accessories. The results from these tests were within expected limits and provide reasonable assurance that the device is safe for its intended use from a toxicological standpoint.

2. Microbiology: The present PMA includes, by reference to PMAs N17-375 and N17-554, the results outlined in "Microbiological Guidelines and Criteria for Testing Contact Lenses Made of New Polymers," an FDA Guideline. The tests included, where applicable, the culturing of the lens, lens case, and associated solutions. The effectiveness of the lens disinfection procedure was evaluated using chemical disinfection regimens. The test results demonstrated that chemical disinfection regimens are effective in disinfecting the lens.

   The safety of this lens, when used on a daily wear basis, was established in the previously approved PMAs, N17-375 and N17-554.

B. Clinical:

The clinical studies on extended wear were conducted in accordance with "Clinical Guidelines for Corneal Contact Lenses of New Material for Non-diseased Eyes," an FDA Guideline.

Study Population

A total of 429 aphakic patients (581 eyes) were enrolled in the aphakic extended wear clinical study. There were 223 females and 206 males, of whom 90 percent were at least 51 years of age. Patients were divided into standard and non-standard groups depending on their baseline best corrected visual acuity as

19

determined with a phoropter. Both groups met study protocol requirements, and the majority (290, 67.6%) were wearing a soft contact lens on a daily basis before entering the study. Patients with better than 20/70 best corrected visual acuity were placed in the standard group, and patients with 20/70 or worse best corrected visual acuity were placed in the non-standard group. Seven eyes in the non-standard group had better than 20/70 binocular visual acuity, but the classification was by eyes, not patients. Of the 429 patients (581 eyes), there were 353 active patients (470 eyes). Of the active patients, 257 patients (349 eyes) completed more than 6 months of wear, and 96 patients (121 eyes) had completed less than 6 months of wear at the time the PMA was submitted. As discussed on pages 8 and 9, 76 patients (111 eyes) discontinued the study. The total population, by subgroups, is as follows with figures in parentheses referring to eyes:

Enrolled Population

Patients (Eyes)

	Standard		Non-standard		Total	
Enrolled	396	(531)	33	(50)	429	(581)
Females	202		21		223	
Males	194		12		206	
Active (continuing)	333	(441)	20	(29)	353	(470)
Completed 6 months or more	243	(327)	14	(22)	257	(349)
Completed less than 6 months	90	(114)	6	(7)	96	(121)
Discontinued	63	(90)	13	(21)	76	(111)
Completed 6 months or more	7	(10)	0	(0)	7	(10)
Completed less than 6 months	56	(80)	13	(21)	69	(101)

The powers of the SOFTCON® Contact Lens evaluated in this study ranged from +6.50 to +19.5 diopters with over 60 percent in the +13.0 to +16.0 diopter range.

20

Patient Selection Criteria

The participating patients for this study were to meet the following criteria:

1. be aphakic;

2. have need of an optical correction;

3. have otherwise normal eyes and use no ocular medications; and

4. be reasonably expected to obtain improvement in visual acuity with contact lenses.

Patients exhibiting higher than normal amounts of astigmatism, i.e., 3 diopters, were not excluded from the study. Spectacles were to be prescribed to correct near vision and astigmatism.

Study Period

The study period at the time of this submission was 6 months. This is an on-going study involving 18 investigators.

Findings

1. Safety:

Adverse Reactions

In evaluation of the product, an adverse reaction was considered to be a serious vision-threatening problem that was unanticipated, but which might have been attributed to the use of the study product.

Two adverse reactions were reported during this study. One patient developed a pinpoint marginal corneal ulcer. The patient was switched to daily wear of the lens, and visual acuity decreased from 20/30 to 20/40 which is within normal limits. One patient had an inflammatory response characterized by severe edema, severe conjunctival hyperemia, and iritis. This patient was diabetic and had considerable corneal scarring, which was observed at the initial visit. The patient was switched to daily wear of the lens, and visual acuity decreased from 20/50 to 20/70. This reduction was considered a fluctuation due to diabetic changes and not lens related.

Slit Lamp Findings

A positive slit lamp finding was considered to be a routinely occurring complication that would be expected with or without the presence of contact lenses. Slit lamp

21

findings were reported in grades 1 through 5 for all findings except edema, which was graded 1 through 11, as outlined in the FDA clinical guidelines. The degree of severity can range from very slight to serious. At the least severe (Grades 1-2; mild, minimal effects), the findings present no medical concern and are noticeable only by microscopic slit lamp examination. In a severe state (Grades 4-5; serious conditions) the findings require medical treatment.

Slit lamp findings for standard patients having greater than 6 months of lens wear experience revealed no significant increase in frequency or severity from initial to final visit. The grades of corneal edema were stable from baseline to last visit. There was an increase in the incidence of staining; however, most of these were grade 1, and more than 50% of the baseline observations and 68% of the last visit observations were reported by one investigator. No patient was discontinued because of staining. The prevalence of injection remained stable, while the number of observations of vascularization showed a decrease. The slit lamp observations for standard patients with 6 months or more of lens wear are shown in Table 1.

The slit lamp observations for standard patients with less than 6 months of lens wear showed vascularization as the primary observation (Table 1). This remained relatively stable throughout the study as did all other findings except edema which showed an increase at the last visit. One patient developed folds in Descemet's membrane (grade 9 edema) after about 2 months of wear. Such a fold is generally considered to be due to at least 8% corneal edema; however, no edema was apparent. When contacted by the monitor, the investigator was not alarmed about the observation, and the patient continued to wear the lens. Slit lamp readings at 6 months were negative for this patient.

Table 1

	243 Standard Patients (≥ 6 months in study)		90 Standard Patients (< 6 months in study)	
Slit Lamp Observation	Initial Visit	Final Visit	Initial Visit	Final Visit
Edema	8	12	2	6
Injection	32	29	4	4
Vascularization	54	44	14	13
Staining	21	41	3	5
Conjunctivitis	1	2	0	0
Other	34	28	5	5

27

The incidence of slit lamp findings in the non-standard group who completed 6 months of lens wear did not differ significantly from the standard group. One of the non-standard patients, with a history of macular degeneration, did have a grade 10 corneal edema at the final visit. There was no prior history of corneal edema, and the condition subsequently cleared 3 months later. The non-standard patients with less than 6 months wear showed almost no occurrence of slit lamp observations at either the initial or final visit. The reported grades of staining and injection and their relative frequency in all subgroups are not significant and are comparable with those experienced with soft contact lens use. Positive slit lamp findings observed at the final visit appear in Table 2 below. Slit lamp findings for discontinued patients in both standard and non-standard groups were comparable with slit lamp findings for continuing patients in both groups.

Table 2

Slit Lamp Observation	Grade	Standard Patients > 6 months in Study	Standard Patients < 6 months in Study	Non-standard Patients > 6 months in Study
Edema	1	5	1	0
	2	2	0	1
	3	0	0	1
	5	5	4	0
	6	0	0	1
	9	0	1	0
	10	0	0	1
Injection	1	29	3	1
	2	0	1	0
	3	0	0	1
Vascularization	1	21	6	1
	2	17	6	3
	3	2	0	0
	5	4	1	1
Staining	1	39	2	0
	2	2	1	0
	4	0	2	0
	5	0	0	1
Conjunctivitis	1	2	0	0
	2	0	0	1
Other*		20	5	1
		8	0	0

*The patients with the conditions listed under "Other" presented these findings at their initial visit. These conditions include:

corneal dystrophy, blepharitis, scar, map dot dystrophy, guttata, corneal opacity, pterygium, Decemet Rupture, and anterior synechia. The standard patients with guttata (10) were stable throughout the study. These complications are not graded as are the specified complications.

Conclusion:

The small number of reported adverse reactions (2) along with the overall low incidence of positive slit lamp findings confirm the safety of this lens as determined by the original investigation of the SOFTCON® (vifilcon A) Contact Lens. The change in the use of the lens from daily wear to extended wear by the same patient population does not increase the safety risk over previously approved uses.

2. Effectiveness:

Visual Acuity

The majority (99%) of the 429 patients (581 eyes) enrolled in the standard group (396 patients, 531 eyes) and in the non-standard group (33 patients, 50 eyes) had uncorrected visual acuity of 20/200 or worse.

The number of standard patients (better than 20/70 best phoropter corrected vision), as reported by eyes, who completed 6 months in the study and achieved, without overrefraction, 20/40 or better vision using the SOFTCON® Contact Lens was 235 (72%). Of the standard patients who had completed less than 6 months of wear, 81 (71%) achieved a visual acuity of 20/40 or better without overrefraction at the last visit. The visual acuity data for patients who completed less than 6 months in the study are consistent with the results for patients who completed 6 months or more of lens wear. The non-standard patients (20/70 or worse best phoropter corrected vision) did not achieve nearly as good an improvement in visual acuity as the standard patients, i.e., only 13.8% achieved a visual acuity of 20/40 or better.

24

Table 3

Final Visual Acuity	Standard Patients: Eyes > 6 months		Standard Patients: Eyes < 6 months		Non-Standard Patients: Eyes Active	
	#	%	#	%	#	%
20/20 or better	45	13.8	18	15.8	0	0.0
20/25	65	19.9	25	21.9	2	6.9
20/30	72	22.0	20	17.5	0	0.0
20/40	53	16.2	18	15.8	2	6.9
20/50	34	10.4	14	12.3	3	10.3
20/60	14	4.3	7	6.1	1	3.4
20/70	22	6.7	5	4.4	2	6.9
Worse than 20/70	22	6.7	7	6.1	19	65.5

The visual acuity data available for patients who discontinued the study show that 38 (51%) of the standard patients achieved a visual acuity of 20/40 or better with the SOFTCON® Contact Lens. The standard patients again show a much greater improvement with the SOFTCON® Contact Lens than the non-standard patients (See Table 4).

Table 4

Discontinued Patients

Final Visual Acuity	Standard		Non-Standard	
	#	%	#	%
20/20 or better	8	10.8	0	0.0
20/25	3	4.1	1	5.3
20/30	14	18.9	0	0.0
20/40	13	17.6	1	5.3
20/50	10	13.5	1	5.3
20/60	5	6.8	2	10.5
20/70	3	4.1	2	10.5
Worse than 20/70	18	24.3	12	63.2
VA not reported	16	21.6	2	10.5

Conclusion:

Standard group patients showed the greatest improvement with the SOFTCON® Contact Lens. The number of standard patients whose visual acuity remained 20/40 or better after 6 months of wear in this study (72%) is comparable to studies reported for other approved aphakic extended wear contact lenses. The standard patients achieved a significantly better improvement in visual acuity than the non-standard patients (20/70 or worse best phoropter corrected vision).

21

Wearing Time

Wearing time under the protocol was for 30 continuous days or longer, and the average lens wearing time was 42 days before removal. A few investigators removed the lenses on an unscheduled basis. The primary reasons for unscheduled removals were discomfort and irritation. The average amount of time out of the eye was 15.7 hours.

Conclusion:

This period is comparable with the wearing time reported in studies for other approved extended wear soft contact lenses.

Discontinued Patients

A total of 76 patients (111 eyes) including 63 standard patients (90 eyes) and 13 non-standard patients (21 eyes) discontinued during the course of the study. Six patients were discontinued for complications which included:

Table 5

Complications for Discontinued Standard Patients	Number
Vascularization (Grades 1 and 3)	2
Edema (Grades 4 and 7)	2
Vitritis (Grade 5)	1
Injection (Grade 2)	1
Total	6

The incidence of discontinuance, however, appears to have been influenced by the nature of the patient population. Approximately 50% of the patients enrolled in the study had preexisting medical conditions at the initial visit, i.e., hypertension, diabetes, and hay fever, all of which may result in ocular problems.

In the standard group, the majority (56%) of patients who discontinued did so before 8 weeks in the study. In the non-standard group, 11 of the 13 discontinued patients left at or before 12 weeks of lens wear. In the standard group there were 89 responses for patient discontinuance. Patient motivation, accounted for 63% of discontinuance; uncontrollable reasons such as death, disease, or senility accounted for 21%; and lens-related discontinuance including complications (Table 5) and poor visual acuity accounted for 16%.

Conclusion:

The reasons for discontinuance in this study are similar to the reasons for discontinuance reported in other aphakic extended wear contact lens studies.

Lens Replacements

Lens replacement data for the 429 standard and non-standard patients (581 eyes) enrolled in the study and fitted with the SOFTCON® Contact Lens showed that 384 lenses were replaced for 409 reasons. The primary reasons for lens replacement were: lost lenses (32%), fit changes (24%), poor visual acuity (21%), deposits (11%), and split lenses (5%). The incidence of lens replacement to improve visual acuity or fit diminished as the investigators fitted more patients and became more accustomed to fitting the extended wear SOFTCON® Contact Lens.

Conclusion:

The number and reasons for lens replacement are not significantly different from data presented in studies for other approved contact lenses.

Patient Responses

The patients' subjective responses to the lenses were reported at baseline and last visit for both standard and non-standard patients. Both groups reported that the lens was very comfortable. Patient complaints relating to fitting, i.e., variable vision and excessive movement, decreased as investigators gained experience in fitting the SOFTCON® lenses.

VI. Conclusion Drawn from the Studies

The data demonstrated that the SOFTCON® Contact Lens is safe and effective for extended wear in the correction of visual acuity due to aphakia.

VII. Panel Recommendation

On May 25, 1982, the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel unanimously recommended approval subject to the conditions that all administrative requirements be met and that the applicant be in compliance with the device Good Manufacturing Practice (GMP) Regulations. The applicant has met all of these conditions.

VIII. FDA Decision

FDA concurred with the Section recommendation and approved the application and final labeling on . The device's shelf-life has been established and approved at 5 years. In an on-site inspection on November 4, 5, and 6, 1981, the firm was found to be in compliance with the device GMP Regulations.

IX. Potential Adverse Effects of the Device on Health

Potential adverse effects on health resulting from the use of soft contact lenses are set forth in the package insert under "ADVERSE REACTIONS" (Attachment A).

X. Approval Specifications

A copy of the package insert is included (Attachment A). In addition to the standard "Conditions of Approval" (Attachment B), FDA approval is subject to compliance with the following:

1. The sale, distribution, and use of the device shall be restricted to prescription use in accordance with 21 CFR 801.109.

2. In addition to the requirements listed in the "Conditions of Approval," the applicant shall continue the clinical study and submit data quarterly to the FDA until at least 500 aphakic patients have completed 5 years of extended wear. At the completion of this study, the applicant shall submit to FDA a cumulative report of the results from all patients enrolled in the clinical study. Thereafter, the applicant shall submit to FDA post-approval reports quarterly for the first year, semi-annually the second year, and annually thereafter.

Copies of all approved labeling are available to interested persons for inspection at:

Food and Drug Administration
Office of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Attachments

Summary of Basis of Approval

NDA 17-554

Drug Generic Name: vifilcon A hydrophilic contact lens

Applicant: Warner-Lambert Company
Morris Plains, N. J. 07950

Drug Trade Name: Softcon Corrective Hydrophilic Contact Lens

I. Indications: The correction of visual acuity in persons with non-diseased eyes and in aphakia. It is indicated for persons who have spherical ametropias, refractive astigmatism usually 1.50 diopters or less and/or corneal astigmatism of 2.00 diopters or less.

II. Dosage form, route of administration

Hydrophilic soft contact lens applied topically to the eye. The lenses may be worn up to all waking hours.

III. Manufacturing and Controls:

A. Manufacturing and Controls: The specifications and test methods for the lens blanks, finished lens and ancillary materials are satisfactory. The description of the manufacturing procedure is adequate.

B. Stability Studies: Data on eleven lots for periods exceeding five years indicate a stable product. The data supports a five year expiration date.

C. Methods Validation: Since classical methods validation testing is not feasible on this type drug, the requirement for submission of samples was waived.

D. Labeling: Final printed labeling is satisfactory as to format.

E. Establishment Inspection: Memo dated August 18, 1977, and a re-evaluation received by telephone on May 2, 1978 indicates that the firm is in compliance with Current Good Manufacturing Practice Regulations.

F. Environmental Impact Analysis Report (EIAR): None required at time of filing. Numerous lenses of similar nature are marketed and negligible environmental impact exists. There is no impact anticipated.

IV. Pharmacology

1) Preclinical studies submitted to date support safety of use of Softcon soft contact lenses in conjunction with the Burton & Parsons cold disinfection system (Preflex, Normol and Flexsol).

V. Microbiology:

This lens application has had a long history since the original application for approval. The various lens disinfection regimens using hydrogen peroxide were not approved. This current application is a re-submission to permit approval with an already-approved chemical disinfection system for other lenses, Preflex, Flexsol, Normol. This system is on the market and has been approved as an NDA.

Studies supporting approval

1. Preservative effectiveness studies for all solutions have been performed and show effectiveness.

2. Uptake of preservatives from the lens has been determined and is in the same range as that for other lenses.

3. The disinfection effectiveness has been determined as part of another NDA.

VI. Medical

Several reviews of the clinical studies with this lens have been done at various times over the years since this application was originally submitted. There has not been any clinical basis for non-approval since the clinical studies submitted conform to the FDA Clinical Guidelines.

The application has been approvable on a clinical basis for several years while the objection has been based on the effectiveness and safety of the disinfection system with hydrogen peroxide.

However, when this application was reviewed by the Ophthalmic Device Committee, questions were raised concerning a high infection rate with one initial investigator. The questions raised about follow-up and inclusion of this investigator's results in averages of adverse reactions have been resolved and the reactions seem to have been peculiar to the specific investigator.

30

The clinical study was conducted by seven investigators and involved 227 patients (74 male, 153 female) who completed 6 months or more of lens wear. A visual acuity of 20/30 or better was achieved in 97% of the patients. The overall incidence of positive slit lamp findings was 12%. All symptoms associated with slit lamp abnormalities were transitory in nature. The majority of lens replacements were because of handling failures. There were no clinical reports of eye infection throughout the course of the study. There were no other adverse reactions reported during the course of the study.

VII. Approved Package Insert - See attached

Labeling

IMPORTANT

Please read carefully and keep this information for future use.

Soft-55 & Soft-55 EW Aphakic (vifilcon A)

Soft (hydrophilic) Contact Lenses for Daily Wear and/or Extended Wear

IMPORTANT - Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

DESCRIPTION: The Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses are spherical lenses for nearsightedness (myopia), farsightedness (hyperopia) and after cataract surgery (aphakia). The Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses are a hemispherical shell of the following dimensions:

- Chord Diameter: 14.0mm, 14.5mm
- Base Curve: 7.8, 8.1, 8.4 and 8.7mm
- Powers: -8.00 to +18.00 D
- Center Thickness: 0.10mm to 0.64mm (dependent on power)

Vifilcon A is made of copolymer of 2-hydroxyethyl methacrylate and povidone, USP. The chemical name is: Poly (2-hydroxyethyl methacrylate-co-ethylene dimethacrylate-co-methacrylic acid-g-povidone). When fully hydrated, the lens contains about 55% water by weight

The physical properties of the hydrated lenses are:

- Specific Gravity 1.12 hydrated
- Refractive Index at 25° 1.415
- Light Transmittance 96.9%
- Water Content 55% by weight in normal saline
- Oxygen Transmissibility 22.7×10^{-9}

(cm/sec) (ml O_2/ml x mm Hg) at 23° C.

ACTIONS: In its hydrated state, the soft contact lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS (USES): Soft-55 Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. Soft-55 Soft (hydrophilic) Contact Lenses may be worn by persons who may exhibit astigmatism of 2.00 D or less that does not interfere with visual acuity.

Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses are indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses are indicated for the correction of visual acuity in aphakic persons (after cataract surgery) with non-diseased eyes that are myopic or hyperopic. Soft-55 EW Aphakic lenses may be worn by persons who may exhibit astigmatism of 2.00 D or less that does not interfere with visual acuity.

The lenses may be disinfected using chemical disinfection system only.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE this contact lens when any of the following conditions exist:

- Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Any active corneal infection: purulent (pus) bacterial, fungal, or viral infection.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Allergy to any ingredient, such as thimerosal or mercury, in a solution which must be used to care for the lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- If eyes become red or irritated
- Any medication which is contraindicated

WARNINGS:

Patients should be advised of the following warnings pertaining to contact lens wear:

The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis (corneal ulcers) for contact lens users. Patients should be informed that eye problems including corneal ulcers can develop rapidly and lead to loss of vision. If the patient experiences eye discomfort, excessive tearing, vision changes, redness of the eye or other problems with their eyes, they should be instructed to immediately remove their lenses and promptly contact their eye care practitioner. It is recommended that contact lens wearers see their eye care practitioner twice each year or as directed.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers. If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner.

PRECAUTIONS: Special Precautions for Eyecare Practitioners:

Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lenses easily or should have someone else available to remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

EYECARE PRACTITIONERS SHOULD CAREFULLY INSTRUCT PATIENTS ABOUT THE FOLLOWING CARE REGIMEN AND SAFETY PRECAUTIONS:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Do not use thermal (heat) lens care systems with Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses. Do not mix chemical (not heat) lens care systems.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Soft-55/Soft 55 EW Aphakic Soft (hydrophilic) Contact Lenses and those prescribed by the eyecare practitioner.
- Always use FRESH unexpired lens care solutions.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Do not use saliva or anything other than the recommended solutions to wet your lenses.
- Nail polish remover and its fumes can damage your lenses. Therefore do not expose your lenses to nail polish remover.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- To prevent your lenses from becoming dry (dehydrated), always keep them completely immersed in the recommended storage solution when the lenses are not being worn. Follow the lens care directions for Care for a Dried Out Lens if your lens surface does become dry (dehydrated).
- If the lens sticks (stops moving) on the eye, follow the directions on Care for a Sticking Lens. The lens must move freely on the eye for continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Never use tweezers or other tools to remove the lens from the lens container. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always handle lenses carefully and avoid dropping them.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Do not swim with your lenses on your eyes.
- Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always inform the doctor (health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform employer of being a contact lenses wearer. Some jobs may require use of eye protection equipment or may require that patient not wear contact lenses.
- DO NOT WEAR SOFT-55/SOFT-55 EW Aphakic Soft (hydrophilic) Contact Lenses while sleeping unless your eye care practitioner has prescribed an extended wear schedule.
- As with any contact lens, follow-up visits are necessary to assure health. Patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS: The patient should be informed that the following problems may occur:

- Eyes sting, burn, or itch (irritation) or other eye pain
- Eye infection
- Corneal swelling
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

WHAT TO DO IF A PROBLEM OCCURS:

a IMMEDIATELY REMOVE LENSES.
b If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, DO NOT put the lens back on eye. Place the lens in the storage case and contact the eye care practitioner.
c If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them.
d After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult an eye care practitioner.

WHEN ANY OF THE ABOVE SYMPTOMS OCCUR, A SERIOUS CONDITION SUCH AS INFECTION, ABRASION, CORNEAL ULCER, NEOVASCULARIZATION, OR IRITIS MAY BE PRESENT. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage. As with any contact lens, corneal thickening and abrasions may occur if the lens does not fit properly or if wearing time is excessive.

FITTING: Conventional methods of fitting contact lenses apply to these soft contact lenses. For a detailed description of the fitting technique, refer to the Professional Fitting Guide, copies of which are available from:

Biocompatibles, Inc
Lombart Lenses Division
1215 Boissevain Avenue
Norfolk, Virginia 23507
(800) 446-8301

CAUTION: FEDERAL (U.S.A.) LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.

WEARING SCHEDULE: THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, also are extremely important.

- DAILY WEAR - (Less than 24 hours, while awake). All Soft-55/Soft-55 EW Aphakic lenses are suitable for daily wear.

The Soft-55 Soft (hydrophilic) Contact Lenses are indicated for Daily Wear. The maximum suggested wearing time for these soft contact lenses is:

Day	Hours
1	4
2	6
3	8
4	10
5	12
6	14
7	All waking hours

THE LENSES SHOULD BE REMOVED FROM THE EYE BEFORE SLEEP.

- EXTENDED WEAR - (Greater than 24 hours including while asleep). The wearing time of all Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses used for extended wear should be determined by the eye care practitioner. Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses can be prescribed for extended wear periods of one to seven days between each removal, cleaning and disinfection/neutralization cycle.

- CAUTION: Not every patient is able to wear Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses on an extended wear basis even if able to wear the same lenses for daily wear. Start daily wear before extended wear if so directed by your eye care practitioner. You should remove, clean and disinfect/neutralize your lenses as prescribed by your eye care practitioner. You should never exceed your prescribed wearing schedule regardless of how comfortable your lenses feel.

WITH EXTENDED WEAR, THERE MAY BE INCREASED RISK OF EYE PROBLEMS SUCH AS IRRITATION, INFECTION, CORNEAL THICKENING, AND CORNEAL ULCERS. THEREFORE, PERIODIC CHECKUPS ARE EXTREMELY IMPORTANT.

LENS CARE DIRECTIONS:

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)
Basic Instructions:

- Always wash, rinse and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Lens care is the same whether or not lenses are tinted.
- Use the recommended system of lens care, only chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling. Do not substitute products unless otherwise recommended by your eye care practitioner.
- Do not use saliva or anything other than the recommended solution for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribe by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Note: Some solutions may have more than one function which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Care Regimen Products
Hydrogen Peroxide Lens Disinfection
AOSEPT® System

Product	Purpose
CIBA Vision Cleaner or MiraFlow® Extra Strength Daily Cleaner	Cleaning
AOSEPT® Solution	Disinfecting/Neutralizing
AODISC®	Neutralizing
CIBA Vision Saline	Rinsing
AOSEPT® Lens Holder and Cup	Lens Case for Disinfection/Neutralization
CIBA Vision Lens Drops	Lubricating

AOSEPT® System Instructions
For complete product use information refer to AOSEPT® Package Insert

The lens care products listed above are recommended for use with Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens.

Clean, rinse and disinfect/neutralize your contact lenses each time you remove them. Before handling your contact lenses, always wash your hands thoroughly and dry them with a clean, lint-free towel. To clean, rinse and disinfect/neutralize your lenses, the following two procedures must be followed.

PROCEDURE ONE - Clean your lenses after each removal
1. Clean the surface of the right lens with MiraFlow® Extra-Strength Daily Cleaner or other recommended cleaner. Follow the product instruction included with the cleaner.
2. Rinse the lens thoroughly with a steady stream of CIBA Vision Saline and place the right lens on the dome in the unmarked side of the lens holder (See note below.)
3. Repeat steps one and two with the left lens and place the lens on the other dome of the lens holder marked "L".

NOTE: To prevent damage to your lens, center the lens on the dome in the lens holder. Be sure the lens does not touch the basket rim, then close the basket lid.

PROCEDURE TWO - Disinfect/neutralize your lenses, AFTER steps 1-3 above have been completed.
1. An AODISC® must always be present to neutralize the AOSEPT Solution. If your cup has a lens holder with a stem, place the AODISC onto the stem. If your cup has a lens holder without a stem, place the AODISC in the bottom of the cup.
2. After you've placed your lenses in the lens holder, fill the AOSEPT Cup with AOSEPT Solution TO THE FILL LINE AND immediately place the lens holder in the cup. Tighten (turn clockwise) the cap and shake gently. DO NOT OVERFILL. Overfilling the cup will cause the AOSEPT Solution to overflow from the cup.
3. Allow the lenses to soak for a minimum of six (6) hours or overnight. After a minimum of six (6) hours, your lenses are ready to wear. If your lenses have been soaking in the AOSEPT Cup for more than 24 hours, you must repeat the disinfection/neutralization procedure again before wearing your lenses.
4. You must rinse your lenses thoroughly with CIBA Vision Saline prior to lens insertion on the eye.
5. After putting your lenses on, always discard the neutralized AOSEPT Solution from the AOSEPT Cup, rinse with AOSEPT Solution or CIBA Vision Saline and leave the cup open to air dry. This rinsing and air drying will help to keep your cup free of microbial contaminants. The lens holder should be inverted (outside the cup) so it's not laying on its side.

DIRECTION NOTES:
a) If bubbles flow from the hole on the top of the cap of the lens holder, this indicates that you have overfilled the cup or that you may not have thoroughly rinsed the cleaner off your lenses.
b) Never rinse your lenses in AOSEPT Solution and put directly on the eye.
c) Lenses must always be disinfected/neutralized for a minimum of six (6) hours in the AOSEPT Cup with the AODISC and rinsed with saline before putting your lenses on.
d) The AODISC must be replaced with a new AODISC after 100 uses or three (3) months of daily use.
e) If you use an enzymatic cleaner be sure to clean, disinfect/neutralize and rinse your lenses before insertion on the eye.
f) Only an enzymatic cleaner that is recommended for use with hydrogen peroxide disinfecting solutions, such as ULTRAZYME™, can be used with the AOSEPT Solution in the AOSEPT Cup. (NOTE: You must rinse your lenses with saline after enzyming.)
g) To prevent contamination and to help avoid serious eye injury, always empty and rinse lens case with fresh, sterile rinsing solution and allow to air dry.
h) Enzyme cleaning does not replace routine cleaning and disinfection. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation. For Enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:
Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

CARE FOR A DRIED OUT (DEHYDRATED LENS):
If your with Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses is off your eye and exposed to air for 30 minutes or longer, it will become dry and brittle.

To rewet your lens:
a) Handle the lens carefully
b) Place the lens in its storage case and SOAK the lens in a rinsing and storage solution recommended for use with soft contact lenses for at least one half hour.
c) Clean and disinfect the rewetted(rehydrated) lens using the lens care system recommended by your eyecare practitioner.
d) If after soaking, the lens does not become soft, if the surface remains dry, DO NOT USE THE LENS, but contact your eyecare practitioner.

CARE FOR A STICKING LENS - If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended rinsing or lubricating solution. Wait until the lens begins to move freely on eye before removing it. If non-movement of the lens continues, the patient should immediately consult the eyecare practitioner.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED - Each lens is sterilized and supplied in a glass vial containing sterile isotonic saline solution. The glass vial is marked with the base curve, dioptric power, diameter, manufacturing lot number of the lens and expiration date.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing Soft-55/Soft-55 EW Aphakic Soft (hydrophilic) Contact Lenses or experienced with the lenses should be reported to:

Biocompatibles, Inc
Lombart Lenses Division
1215 Boissevain Avenue
Norfolk, VA 23507 (USA)
1-800-446-8301

November, 96